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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,899	12/29/2000	Frank J. Bunick	MCP-0262	9623

7590 08/19/2002

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EXAMINER
EVANS, CHARESSE L

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/19/2002 6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/752,899	Applicant(s) BUNICK	
	Examiner Charesse L. Evans	Art Unit 1615	

-- The MAILING DATE of this communication appears on th cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's amendment and remarks filed June 6, 2002.

Acknowledgement is made of the typographical correction in claim 13. The objection of record of claim 13 is withdrawn.

Claims 1-13 are pending in this Action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order

for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentine (US 4,684,534) in view of Puglia et al (US 4,327,076). The claims are directed to a tablet comprised of an active ingredient and a matrix comprised of dextrose monohydrate and sucralose.

Valentine teaches a chewable tablet comprised of active ingredients such as antacids, analgesics, cough medicine and drugs (column 3, lines 8-29). The chewable tablet also contains dextrose monohydrate and sucrose (Abstract). Valentine does not expressly teach sucralose, however, it would be an obvious variation to substitute sucrose for sucralose, as sucrose is the starting material for sucralose (Liu et al, WO 99/47126, page 13, line 15).

While the reference is silent regarding percent weight of water-soluble polymeric binders, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

With respect to the particle size, the dextrose monohydrate passed 50 mesh or particle sizes less than about 300 microns (column 9, lines 20-23) while the dextrose

particles comprise from about 90 to 99 percent by weight of the referenced agglomerate (column 2, lines 42-44). Although the reference discloses that smaller particle sizes are desired, the active ingredient can have particle sizes larger than about 50 microns. One having ordinary skill in the art would have been expected to determine the optimum particle sizes during routine experimentation.

The tablet of the reference can further contain lubricants and flavors (column 4, lines 14-16). Example XIII describes a direct compression agglomerate in column 13, lines 21-55. With respect to the presence of binders in the referenced tablet, binders are present from about 1 to 10% (column 17, claim 7, line 47).

Valentine does not expressly teach fats, however, Puglia teaches a compressed chewable tablet comprised of fats employed in amounts within the range of from about 2 to 45% (column 4, lines 61-63). It would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Puglia into the teachings of Valentine because Puglia teaches that employing fats into the chewable tablet compositions would provide the expected result of improved taste.

Response to Arguments

Applicant's arguments filed June 6, 2002, have been fully considered but they are not persuasive. Applicant appears to argue that the claimed invention is different from the cited prior art in that the prior art discloses a tablet having a harder outer shell and a softer interior. That may be the case, however, it still reads on applicant's claims. Applicant is claiming a tablet capable of being chewed. The art discloses a chewable tablet.

Applicant also argues that the cited prior art does not teach less than 5% fat or that the matrix be substantially free of non-saccharide, water soluble polymeric binders within the chewable tablet. Examiner disagrees with applicant's position. Puglia ('076) teaches a compressed chewable tablet comprised of fats within the range of from about 2% to 45% in column 4, lines 61-63. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955). Further, regarding the binder, applicant claims that the tablet be "substantially free" of water-soluble binder. "Substantially free" reads on the amount of binder being very low in concentration. Binders are present from about 1 to 10% ('534 – column 17, line 47).

Finally, applicant argues that sucrose would not be readily interchangeable with the sucralose that is taught in the Valentine prior art reference. It is well-known in the art that sucralose is a high intensity sweetener. Thus, it would be an expected result that including a less intense sweetener will yield an invention that is less sweet. How is this result different from the prior art? It would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute sucralose taught in Valentine within a gum that utilizes sweeteners for its art intended purpose. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. Applicant is requested to present data demonstrating why the sucralose does not work compared to why the sucrose only works.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory

period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 703-308-6400. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Charesse Evans
August 14, 2002